REMARKS

By this amendment, claims 1, 3, 5-9, 11 and 14 have been amended, and claim 4 has been canceled. The amendment of claim 6 places that claim in independent form. Amendments to the Specification and Abstract have been made, as requested by the Examiner.

Claims 1-6, 8 and 11-15 were rejected under 35 U.S.C. §102(a) over Naghavi et al. The amendments to the claims were made to overcome the rejections under 35 U.S.C. §112, second paragraph and to better describe the way in which the instant apparatus is constructed in the way in which it operates. More particularly, whereas the Naghavi apparatus may be considered a "passive" design in the sense that, by pushing on a proximal manually operated control, the basket structure emerges from the catheter and automatically expands due to the use of shape-memory alloy, the instant invention is "active" in the sense that, by *pulling* on the manually operated control, the basket expands, and by pushing on the control, it retracts. As such, once the presentation element(s) have been pushed out of the distal tip of the catheter, they remain exposed and expand and contract by pulling and pushing on a sliding filament which extends from the proximal end.

In one embodiment of the instant invention, namely, the embodiment of claim 1, the distal end of the filament is coupled to the distal end of each presentation element, causing each element to bow outwardly and collapse inwardly as the filament is pulled and pushed, respectively. In a different embodiment, that of claim 6, now in independent form, the distal ends of the presentation elements are unattached, but nevertheless, in this embodiment as well, by pulling on the filament, being attached to a plunger or flared tip, causes the fingers to expand and contract. These structures and functions as now claimed fully distinguish over the Naghavi, such that anticipation is precluded.

Claims 1, 4-6, 8 and 9 were rejected under 35 U.S.C. §102(b) over Brown. However, anticipation is precluded in this case as well, because Brown is limited to optical conduits that engage with the vessel wall, carrying infrared energy to sensors that are located *outside the body*. As such, Brown does not teach or suggest the use of thermoelectric sensors such as thermisters, which use an electrical connection between the sensors, located within the body, and a data acquisition/analysis instrument located outside the body. Given that Brown clearly does not teach each and every element of Applicants' claimed invention, rejection under §102 is inappropriate.

Claim 7 stands rejected over Waldman et al. in view of Brown. It is believed that claim 7 is

A

GIFFORD, KRASS, GROH, SPRINKLE, ANDERSON & CITKOWSKI, P.C. 280 N. OLD WOODWARD AVENUE, STE. 400, BIRMINGHAM, MICHIGAN 48009-5394 (248) 647-6000

allowable for the reasons set forth above, but in addition, it is well settled that in rejecting claims under 35 U.S.C. §103, the Examiner must provide a reason why one having ordinary skill in the pertinent art would have been led to modify the prior art, or to combine references, to arrive at Applicants' claimed invention. There must be something *in the prior art* that suggested the combination, other than the hindsight gained from knowledge that the inventor choose to combine these particular things in this particular way. Uniroyal Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988). The Examiner is also required to make specific findings on a suggestion to combine prior art references. In Re Dembiczak, 175 F.3d 994, 1000-01, 50 USPQ2d 1614, 1617-19 (Fed. Cir. 1999). In this case, Waldman is directed to an endocardial electrical mapping catheter, much larger in size than anything usable in a vessel such as an artery, with goals and solutions to problems that are irrelevant to the teachings of Brown. Likewise, the teachings of Brown are inapplicable to the Waldman et al. invention, thereby precluding *prima facie* obviousness.

Based on the foregoing, Applicants believe all claims are in condition for allowance. The provisional allowability of claim 10 has been noted. Questions regarding this application can be directed to the undersigned attorney at the telephone/facsimile numbers provided.

Attached is a version showing the changes made to the Abstract, Specification and the amended claims.

Respectfully submitted,

By: _____

John G. Posa
Reg. No. 37,424
Gifford, Krass, Groh, Sprinkle,
Anderson & Citkowski, PC
280 N. Old Woodward Ave., Ste 400
Birmingham, MI 48009
(734) 913-9300 FAX (734) 913-6007

Date: Nov. 12, 2002

A

GIFFORD, KRASS, GROH, SPRINKLE, ANDERSON & CITKOWSKI, P.C. 280 N. OLD WOODWARD AVENUE, STE. 400, BIRMINGHAM, MICHIGAN 48009-5394 (248) 647-6000

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE ABSTRACT:

A thermal sensing catheter finds particular utility in detecting and isolating unstable arterial plaque. Miniaturized temperature sensors, preferably in the form of microthermistors, are embedded into expandable presentation elements disposed at the distal end of a catheter. The sensors may then be deployed to measure the surface temperature of the inner wall of coronary arteries or other vessels at multiple sites to identify sites of elevated temperature indicative of unstable plaque. The presentation elements may assume a "hand" type design or an alternate basket-type structure. A plurality of thermal sensors are embedded into the sides of polymeric or metallic sensing elements which expand out from the centerline of a catheter toward the inner vessel walls. [An asymmetric encapsulation technique is preferably used to embed the sensors in close proximity against an outer wall of a sensing arm, while maintaining an insulative backing to reduce the effect of blood temperature on the backside of the arms excessively influencing plaque temperature measurements. The catheter assembly interfaces to a data box receiving signals from the sensing elements. The data box includes a display to present the calibrated readings from the sensors, as well as memory capabilities to store data for later download through a port incorporated in the housing. The output of the data box is provided to a computer, preferably in real-time and through the same port, to permit full-screen display of the thermal data. In either mode, a full recording of a procedure is saved for later analysis.]

IN THE SPECIFICATION:

Page 8, lines 8-9:

FIGURE 1D shows how the insulting capability of an expanding pad increases with increasing outside diameter (O.D.)for a given sensor size;

Page 16, lines 11-18:

As with the other embodiments disclosed herein, preferably the materials [302] forming the [arms] fingers 302 in this case are insulated against blood flow temperature variations so that the sensors 304 accurately record wall temperatures without being adversely affected by blood flow. This

A

embodiment is also not restricted to the use of two fingers, but more may be used such as the three fingers shown in Figure 3C. In addition, as with the other embodiments described herein, the embodiment described with reference to Figures 3A through 3C may also be calibrated so as to provide a user with an estimate of inner vessel diameter as well as localized temperature.

Page 16, line 19 to page 17, line 4:

Figures 4A through 4D illustrate preferred hand-type embodiments of the invention. In Figure 4A, a sensing head 402 includes one or more sensing cantilevered arms 404, each with a thermal sensor, surrounding a central member 410. The arms and central member are configured such that when the member is pulled from the proximal end, the arms fan outwardly from the contracted state of Figure 4A into a the expanded position, as shown in Figure 4B. Again, the arms are cantilevered to provide a relatively constant and uniform force against the vessel wall in the expanded state while avoiding excess pressure.

Page 19, lines 9-18:

The temperature sensors are preferably embedded slightly below the outer surfaces of the sensing arms or elements, along the surface closest to the inner wall of the vessel. The material covering the thermal sensor on the outer surface of the expanding [are or] element is chosen and configured so as to permit minimal thermal resistance between the thermal sensor and the outer surface of the sensing arm. This may be achieved by having a minimal thickness of material, or by choosing a material of low thermal resistance. In contrast, the bulk material of the expanding element is preferably chosen to have high thermal resistance and to be of a significantly greater thickness than the thickness of the material covering the thermal sensors on the outer surface of the sensing arms.

IN THE CLAIMS:

1. (Amended) A system for sensing the temperature of [an arterial wall or other] a vessel wall, including an arterial wall, the system comprising:

an elongated catheter having a distal end [with a temperature sensing tip] and a proximal end [including a manually operated expansion control];

A

a sliding filament that protrudes from both ends of the catheter, the protruding filament at the proximal end of the catheter acting as a manually operated expansion control;

a [the] temperature sensing tip including one or more presentation elements, each element having a temperature sensor supported thereon;

each [the] presentation [elements] element having a proximal end coupled to the distal end of the catheter and a distal end coupled to the distally protruding end of the filament [being physically coupled to] such that pulling on the manually operated expansion control [, such that operation of the control] causes each element [the elements and temperature sensors] to move from [between] a retracted position [, enabling the temperature sensing tip to be positioned in a section of the vessel to be measured,] to an expanded position enabling the sensor to be placed in contact or immediately proximate to the vessel wall, and pushing on the manually operated expansion control causes each presentation element to return to the retracted position from the [an] expanded position [, wherein the sensors are in contact or immediately proximate to the vessel wall]; and

a data unit operative to receive electrical signals from the temperature sensors and display information indicative of vessel wall temperature [as sensed by the sensors].

3. (Amended) The system of claim 1, wherein the presentation elements are thermally insulative so that the sensors are isolated from [the effects of] temperature fluctuations caused by blood flow or other ambient conditions.

5. (Amended) The system of claim 1, wherein the presentation elements are configured such that blood may continue to flow around the elements when the elements are in the expanded [condition] position.

6. (Amended) [The] A system [of claim 1, wherein the presentation elements are fingers which expand outwardly in response to the manually operated expansion control.] for sensing the temperature of the wall of a vessel including an arterial wall, comprising:

an elongated catheter having a distal end and a proximal end;

a sliding filament that protrudes from both ends of the catheter, the protruding filament at the

A

GIFFORD, KRASS, GROH, SPRINKLE, ANDERSON & CITKOWSKI, P.C. 280 N. OLD WOODWARD AVENUE, STE. 400, BIRMINGHAM, MICHIGAN 48009-5394 (248) 647-6000

proximal end of the catheter acting as a manually operated expansion control;

a temperature sensing tip including a plurality of presentation elements in the form of cantilevered fingers which expand outwardly by pulling on the manually operated expansion control, each element having a temperature sensor supported thereon which is placed in contact or immediately proximate to the vessel wall during the expansion; and

a data unit operative to receive signals from the temperature sensors and display information indicative of vessel wall temperature as sensed by the sensors.

7. (Amended) The system of claim 6, wherein the cantilevered fingers are [cantilevered] configured to provide a relatively constant and uniform force against the vessel wall.

8. (Amended) The system of claim 6, wherein the fingers surround a central plunger coupled to the manually operated expansion control, such that pulling on the plunger causes the fingers to expand outwardly and pushing on the plunger causes the finger to turn to a contracted position.

9. (Amended) The system of claim 8, wherein the plunger is conically shaped [in the area where the plunger causes the fingers to spread].

11. (Amended) The system of claim [8] 1, wherein the temperature sensing tip features a plurality of longitudinal slices [such that the presentation system assumes] forming a basket-like structure which flares out [in response to] when the manually operated expansion control is pulled, and which collapses when the control is pushed.

14.(Amended) The system of claim 13, wherein the temperature sensors are hardwired to the data unit, and the groove extends [grove extend] the length of the catheter to receive the wires.

A